

**Title: Validation of the Comprehensive ICF Core Set for obstructive pulmonary diseases
from the patient's perspective**

Running head: Comprehensive ICF Core Set for OPD

Alda Marques^{1,2*}, Cristina Jácome¹, Ana Gonçalves¹, Sara Silva¹, Carla Lucas¹, Joana Cruz³,
Raquel Gabriel^{1,2}

1 School of Health Sciences, University of Aveiro (ESSUA), Aveiro, Portugal

2 Unidade de Investigação e Formação sobre Adultos e Idosos (UNIFAI), Porto, Portugal

3 Department of Health Sciences (SACS), University of Aveiro, Aveiro, Portugal

Corresponding author: Alda Marques, School of Health Sciences, University of Aveiro
(ESSUA), Agras do Crasto - Campus Universitário de Santiago, Edifício 30, 3810-193 Aveiro,
Portugal. Telephone: 00351 234 372 462. Email: amarques@ua.pt

Conflicts of interest

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Abstract

Objective: This study aimed to validate the Comprehensive International Classification of Functioning, Disability and Health (ICF) Core Set for Obstructive Pulmonary Diseases (OPD) from the perspective of patients with COPD.

Methods: A cross-sectional qualitative study was conducted with outpatients with Chronic Obstructive Pulmonary Disease using focus groups with an ICF-based approach. Qualitative data were analysed through the meaning condensation procedure by two researchers with expertise in the ICF.

Results: Thirty-two participants (female 37.5%; 63.8±11.3 years old) were included in 6 focus groups. A total of 61 (86%) ICF categories of the Comprehensive ICF Core Set for OPD were confirmed. Thirty-nine additional second level categories not included in the Core Set were identified: 15 from the Body Functions component, 4 from the Body Structures, 9 from the Activities and Participation and 11 from the Environmental Factors.

Conclusions: The majority of the categories included in the Comprehensive ICF Core Set for OPD were confirmed from the patients' perspective. However, additional categories, not included in the Core Set, were also reported. The categories included in the Core Set that were not confirmed and the additional categories need to be further investigated to develop an instrument tailored to patients' needs. This will promote patient-centred assessments and rehabilitation interventions.

Key words: Chronic Obstructive Pulmonary Disease; International Classification of Functioning, Disability and Health; Patient's perspective.

1 Introduction

2 Chronic Obstructive Pulmonary Disease (COPD) currently affects 210 million people worldwide
3 (World Health Organization, 2007). This condition is primarily characterised by a progressive
4 airflow limitation however, as the disease progresses, exacerbations and comorbidities, such as
5 cardiovascular diseases, skeletal muscle dysfunction and osteoporosis, contribute to a
6 decreased physical and emotional participation in everyday activities (Vestbo *et al.*, 2013).
7 Thus, it is imperative to systematically assess functioning of patients with COPD to optimise the
8 management of their health condition and, ultimately, improve their quality of life.

9 The World Health Organization (WHO) recommends the use of the International Classification
10 of Functioning, Disability and Health (ICF) to comprehensively assess the health experience of
11 patients living with specific health conditions (World Health Organization, 2001). This
12 classification uses a globally agreed-on language and reflects the biopsychosocial model in an
13 unified view of various dimensions of health (World Health Organization, 2001). However, it is
14 composed of 1424 categories and, therefore, it is not feasible to use in clinical practice (Stucki
15 *et al.*, 2008). To facilitate the implementation of the ICF, Core Sets have been developed (Cieza
16 *et al.*, 2004). Core sets represent a selection of ICF categories describing the prototypical
17 spectrum of problems in functioning of patients with specific health conditions (Cieza *et al.*,
18 2004). For Obstructive Pulmonary Diseases (OPD), under which COPD is the most
19 representative worldwide, two ICF Core Sets are available: the Brief and the Comprehensive
20 (Cieza *et al.*, 2004, Stucki *et al.*, 2004). The Brief ICF Core Set is composed of minimum data to
21 be used at any clinical context (Cieza *et al.*, 2004, Stucki *et al.*, 2004). The Comprehensive ICF
22 Core Set has the ability to collect more information and it is indicated for multidisciplinary
23 assessments in the rehabilitation process (Cieza *et al.*, 2004, Stucki *et al.*, 2004).

24 The current version of the Comprehensive ICF Core Set for OPD has been validated from the
25 perspective of physicians (Jobst *et al.*, 2013) and physiotherapists (Rauch *et al.*, 2009).
26 However, the WHO advocates a patient-centred care model, where patient's expectations,
27 needs and preferences are considered in health and social care planning (World Health
28 Organization, 2005). A key aspect in the validation process is therefore to integrate the patient's
29 perspective (Coenen *et al.*, 2006). A recent study validated the Activities and Participation

component of this ICF Core Set according to the patient's perspective using individual interviews (Marques *et al.*, 2013). Nevertheless, Body Functions, Body Structures and Environmental Factors components were not validated. Therefore, this study aimed to examine to what extent the health experience of patients with COPD is reflected in all components of the current version of the Comprehensive ICF Core Set for OPD.

Methods

Study design

A cross-sectional qualitative study, using focus groups with an ICF-based approach, was conducted with outpatients with COPD. The study received full approval from the Institutional Ethics Committee.

Participants

The sample was recruited from December 2011 to October 2012 in three primary care centres of the central region of Portugal. Patients were eligible if they were: i) diagnosed with COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria (Vestbo *et al.*, 2013); ii) 18 years old or older; and iii) able to understand the purpose and procedures of the study. Patients were excluded if they presented severe psychiatric conditions and/or inability to understand and co-operate.

Data Collection

Potential eligible patients were identified by General Practitioners. The clinic secretaries contacted via telephone all potential participants, explained the purpose of the study and asked about their willingness to participate. If patients agreed to participate, they were invited to attend a meeting with the researchers in their primary care centre where they were informed, both verbally and in a written form, about the study procedures. All patients were included after signing the informed consent form.

Socio-demographic (gender, age, education level, marital status and current occupation) and clinical (lung function) data were first collected. Then, one moderator conducted all focus groups in a non-directive manner. At least one group assistant was present in each focus group to take observational notes of the group interaction and topics of discussion. Both moderator and group assistants were researchers with expertise in the ICF and in conducting focus groups. At the

beginning of each focus group, a brief explanation about the procedures of the session as well as the concept of the ICF was provided. As the ICF-based approach was used, the titles of the ICF chapters included in the Comprehensive ICF Core Set for OPD were presented to the participants using a Microsoft PowerPoint presentation (Coenen *et al.*, 2006, Kirchberger *et al.*, 2009). For each chapter, open-ended questions on possible experienced problems related to COPD were used (*"If you think about your body and mind: what does not work the way it is supposed to? In which parts are your problems?"*, *"If you think about your daily life, what are your problems?"* and *"If you think about your environment and your living conditions: what do you find helpful or supportive? What barriers do you experience?"*). To obtain more information, at the end of each ICF component the participants were asked whether they thought that important information was missing in Body Functions, Body Structures, Activities and Participation or Environmental Factors, respectively (*"What is missing?"*). The presentation order of the ICF chapters in each focus group was randomised. The focus group sessions were digitally recorded and transcribed.

Data analysis

A qualitative analysis was performed independently by two researchers with expertise in ICF following the meaning condensation procedure (Kvale, 1996). Firstly, the full transcriptions were read to obtain an overview of the collected data. Secondly, data were divided into meaning units. A meaning unit was defined as a part of the transcription (few consecutive words or sentences) about the same theme. Therefore, a meaning unit division was rather based on meaning shifts than on grammatical linguistic rules. Thirdly, the concepts contained in each meaning unit were identified. As proposed by the meaning condensation procedure, a meaning unit could contain more than one concept. Then, the identified concepts were linked to ICF categories based on established linking rules (Cieza *et al.*, 2005). One concept could be linked to one or more ICF categories (Cieza *et al.*, 2005). The code *nd* (not defined) was used to describe a concept that was not specific enough to be assigned to an existing ICF category, whereas the code *nc* (not covered) represented concepts not yet included in the ICF (Cieza *et al.*, 2005).

The number of focus groups conducted was determined by data saturation, defined as the point during data analysis when the linking of the concepts of two consecutive focus groups revealed less than 5% additional second level categories (Coenen *et al.*, 2006).

The final decision of the identified ICF categories was based on consensus and then compared with the categories of the current version of Comprehensive ICF Core Set for OPD. Categories included in the Comprehensive ICF Core Set for OPD were confirmed if the same category emerged in the focus groups. Since the ICF categories are arranged in a hierarchical system, the second level categories of the Comprehensive ICF Core Set for OPD were also confirmed when the corresponding third or fourth level category was identified.

Descriptive statistics were used to characterise the sample. To determine the consistency of the qualitative analysis performed by the two researchers, an inter-observer agreement analysis using the Cohen's kappa was performed for each level of the ICF classification (Elliott and Woodward, 2007). Fifteen percent of the qualitative analysis was randomly selected to perform this test (Coenen *et al.*, 2006, Marques *et al.*, 2013). The value of Cohen's kappa ranges from 0 to 1 and can be categorised as slight (0.0-0.20), fair (0.21-0.40), moderate (0.41-0.60), substantial (0.61-0.80) or almost perfect (≥ 0.81) agreement (Landis and Koch, 1977). All statistical analyses were performed using PASW Statistics (Version 18.0, SPSS Inc., Chicago, IL).

Results

Participants

A total of 45 patients were contacted for inclusion in the study, however, 7 refused to participate as they did not perceive the study as relevant and 6 failed to attend the meeting. Thirty-two participants (female 37.5%) were included in 6 focus groups. Participants' mean age was 63.8 ± 11.3 , ranging from 44 to 81 years old. According to the GOLD criteria, 12 (37.5%) participants had mild COPD, 13 (40.6%) moderate and 7 (21.9%) severe to very severe. The characteristics of the participants are summarised in Table 1.

(Insert table 1 about here)

Inter-observer agreement

The agreement between the two researchers was almost perfect for the ICF component (Kappa=0.94; 95% CI 0.78-1), first (Kappa=0.92; 95% CI 0.79-1), second (Kappa=0.96; 95% CI 0.88-1), third (Kappa=0.86; 95% CI 0.71-1) and fourth (Kappa=1) levels.

ICF categories according to the participants' perspectives

A total of 1184 concepts were identified. Of these, 1127 were linked to 167 ICF categories, 76 from the second, 86 from the third and 5 from the fourth levels. For the categories from the third and fourth levels, the correspondent second level category was considered. Thus, the concepts were linked to 98 second level categories. However, 57 concepts could not be linked to the ICF: 10 were coded as *not defined*, 8 as *not covered* (e.g. sputum characteristics; coordinating breathing with talking and walking) and 36 as Personal Factors (e.g. being calm and tolerant; being active; fearing the future).

(Insert figure 1 about here)

A total of 61 (86%) ICF categories included in the Comprehensive ICF Core Set for OPD were confirmed. However, 10 (14%) categories could not be confirmed: 3 from the Body Structures component (s710 structure of head and neck region, s720 structure of shoulder region, s760 structure of trunk); 4 from the Activities and Participation component (d230 caring out daily routine, d465 moving around using equipment, d470 using transportation, d660 assisting others); and 3 from the Environmental Factors component (e340 personal care providers and personal assistants, e575 general social support services, systems and policies and e585 education and training services, systems and policies).

Thirty-nine additional second level categories that are not included in the Comprehensive ICF Core Set for OPD were identified by the participants' perspective. Fifteen belonged to the Body Functions component, 4 to the Body Structures, 9 to the Activities and Participation and 11 to the Environmental Factors.

(Insert tables 2, 3 and 4 about here)

Discussion

1 In this study, the majority of the categories included in the Comprehensive ICF Core Set for
 2 OPD were confirmed from the perspective of patients with COPD. Nevertheless, ten categories
 3 from the Body Structures, Activities and Participation and Environmental Factors components
 4 were not confirmed. Impairments in the structures of the head, neck (s710), shoulder (s720) and
 5 trunk (s760) were not significant categories according to the participants' view. In studies using
 6 the ICF, problems in these structures were also not relevant for patients with COPD, with
 7 prevalences below 30% (Jácome *et al.*, 2013, Ewert *et al.*, 2004). Regarding the Activities and
 8 Participation component, carrying out daily routine (d230) was not an issue to the participants.
 9 However, in a recent study, this activity was one of the most restricted for patients with COPD
 10 (Jácome *et al.*, 2013) and in the study of Marques *et al.* (2013) it was confirmed by patients'
 11 interviews (Marques *et al.*, 2013). This category is defined as *"carrying out simple or complex*
 12 *and coordinated actions in order to plan, manage and complete the requirements of day-to-day*
 13 *duties"* (World Health Organization, 2001). In the present study, instead of reporting difficulties
 14 in carrying out daily routine, patients focused their reports on exemplifying difficulties in
 15 activities of daily routine, which require complex and coordinated actions; e.g., d630 preparing
 16 meals, d640 doing housework and d650 caring for household objects. This has also been
 17 observed in patients with Rheumatoid Arthritis (Stamm *et al.*, 2005). The activities moving
 18 around using equipment (d465), using transportation (d470) and assisting others (d660) were
 19 also not reported by the participants in the current study. One possible explanation is that these
 20 activities may not be part of participants' routines and characteristics and, therefore, they are
 21 not meaningful for patients. A recent study supports these findings (Marques *et al.*, 2013). This
 22 needs careful attention as in the physicians' perspective these categories were also not
 23 relevant, with one exception, the category d470 (Jobst *et al.*, 2013). However, even this
 24 exception had only 39% of agreement using the Delphi technique (Jobst *et al.*, 2013). In the
 25 Environmental Factors, the category e340 personal care providers and personal assistants was
 26 not confirmed. This category was also not validated in the physicians' perspective (Jobst *et al.*,
 27 2013). Personal care providers may not be part of participants' lives, since family carers are
 28 typically the primary source of support to patients (Spence *et al.*, 2008). The other two not
 29 confirmed categories, e575 general social support services, systems and policies and e585

education and training services, systems and policies, have been described as not relevant for patients with COPD in previous studies (Ewert *et al.*, 2004, Jácome *et al.*, 2013). As these ten categories were not confirmed by the participants' perspective, its role in the Comprehensive ICF Core Set for OPD is unclear. These findings, together with the evidence from other studies pointing out to the need of making minor revisions in this Core Set (Rauch *et al.*, 2009, Marques *et al.*, 2013, Jobst *et al.*, 2013), might contribute for the decision on the final version of the OPD Core Set.

Additional categories, currently not included in the Comprehensive ICF Core Set for OPD, were identified. Six of these categories were derived from the chapters b3 voice and speech functions (b330 and b340), s3 structures involved in voice and speech (s310, s330 and s340) and d3 communication (d350), emphasising the relevance of communication problems for patients. The category d330 speaking is already included in the ICF Core Set (Stucki *et al.*, 2004), however, this ICF category alone might not be able to provide sufficient detail to allow a comprehensive assessment of patients' communication problems. Four other categories from the chapter b1 mental functions were also identified, associated to consciousness (b110), temperament and personality (b126), attention (b140), memory (b144) and thought (b160) functions. These functions emerged in participants' report frequently associated with the worsening of respiratory symptoms, *"when I'm with a cold, I have difficulty in concentrating and I feel hopeless"*. Therefore, it may be more important to assess these categories in patients with COPD during exacerbations than in stable periods. Other four categories from the chapter b5 functions of the digestive, metabolic and endocrine systems (b510, b515, b535 and b545) were identified. This is supported by previous literature on the topic which suggests that patients with COPD have concomitant impairments in these systems (Shoikhet Ia and Klester, 2010). Similarly to Marques *et al.* (2013), additional categories from the chapter d7 interpersonal interactions and relationships were identified. This finding reinforces the well-described difficulties that patients with COPD have to face when they are interacting with other people and managing their relationships, including with their family members. Therefore, the inclusion of these categories in the Comprehensive ICF Core Set for OPD should be discussed. Further identified topics were derived from the chapter e5 services, systems and policies, related to architecture (e515), open

space planning (e520), utilities (e530) and social security (e570). These Environmental Factors emerged as barriers in participants' daily life and probably translate the inefficiency of those services, systems and policies to meet patients' specific needs. This topic should be further explored to design appropriate policies to improve the daily life of these patients.

In this study, almost all concepts identified by the participants could be linked to the unified and standard language of the ICF, demonstrating that the ICF broadly represents the most significant impairments in the functioning of patients with COPD. However, eight concepts identified in this study are currently not covered in this classification. For example, the sputum characteristics are not present in the ICF, despite of chronic sputum production being a typical symptom among patients with OPD (Trappenburg *et al.*, 2011, Vestbo *et al.*, 2013). Difficulties in coordinating breathing with walking were also not covered (Bourbeau, 2009). These findings reveal two major limitations of the ICF: some individual experiences are not included in the ICF classification and even when the individual experience is included it may not be with the level of specification required. These limitations have been previously reported (Kirchberger *et al.*, 2009, Marques *et al.*, 2013).

Strengths and limitations

Different approaches for the development of the Comprehensive ICF Core Set for OPD have been applied previously to characterise the functioning of patients with COPD (Jácome *et al.*, 2013), to validate the Core Set in the perspective of health professionals (Rauch *et al.*, 2009, Jobst *et al.*, 2013) and to validate the Activities and Participation component from patients' perspective (Marques *et al.*, 2013). However, the present study is the first to validate the integral Comprehensive ICF Core Set for OPD from patients' perspective and, therefore, it provides an important contribution for the decision on the final version of the OPD Core Set. Nevertheless, there are some limitations that need to be acknowledged. Firstly, most participants had mild and moderate COPD. A sample including a higher proportion of patients with advanced COPD would be more representative of the general population with COPD. Secondly, the sample was composed by Portuguese citizens. As patients in other countries may experience different functioning problems in their daily life due to cultural reasons, future studies using a similar methodology in other countries should be conducted to establish a cross-cultural

perspective. Moreover, COPD is one subtype of OPD and may not be representative of the all spectrum of problems of patients with different OPD. Using this study as a starting point, future studies could be conducted in other countries including patients with others OPD, such as asthma. Lastly, the linking process was performed by two researchers and, in cases of disagreement, consensus was reached. It is believed that this potential bias was reduced, since the inter-observer agreement was almost perfect for the component and also for the second, third and fourth levels of the ICF classification.

Conclusion

The majority of the categories included in the Comprehensive ICF Core Set for OPD were confirmed from the patients' perspective. However, additional categories, not included in the Core Set, were also reported. Further studies are needed to ascertain categories included the Comprehensive ICF Core Set that were not confirmed and to authenticate additional categories. This will contribute to the development of an instrument that integrates the full perspective of patients with COPD and that will enable a patient-centred assessment and planning of tailored health and social interventions. Some limitations of the ICF were also identified and should be considered in future revisions of this classification. The present study contributes for the decision of the final version of the Comprehensive ICF Core Set for OPD and the potential future revision of the ICF.

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4

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1 Table 1 - Characteristics of the participants (n=32).

Characteristics	
Female n(%)	12 (37.5%)
Age (years) M \pm SD	63.8 \pm 11.3
Educational level n(%)	
Primary school	15(46.9%)
Secondary school	11(34.3%)
High school/ University	6(18.8%)
Marital status n(%)	
Married	21(65.6%)
Divorced	3(9.4%)
Widowed	6(18.8%)
Single	2(6.2%)
Current occupation n(%)	
Retired	23(71.9%)
Employed	7(21.9%)
Unemployed	2(6.2%)
Living alone n(%)	5(15.6%)
Current smoker n(%)	13(40.6%)
FEV ₁ (% predicted) M \pm SD	66.1 \pm 23.6
GOLD Classification n(%)	
Mild	12(37.5%)
Moderate	13(40.6%)
Severe/Very severe	7(21.9%)

2 M:Mean; SD:Standard Deviation; FEV₁:Forced expiratory volume in one second.

3 Table 2 – Participants' reporting of ICF categories: Body Functions and Structures.

ICF Code	ICF Category Title	Number of linked concepts
ICF Categories of the Comprehensive ICF Core Set for OPD		
b130	Energy and drive functions	19
b134	Sleep functions	5
b152	Emotional functions	6
b1522	Range of emotion	1
b280	Sensation of pain	34
b2801	Pain in body part	25
b310	Voice functions	17
b410	Heart functions	16

b430	Haematological system functions	3
b435	Immunological system functions	11
b440	Respiration functions	88
b445	Respiratory muscle functions	2
b450	Additional respiratory functions	23
b455	Exercise tolerance functions	89
b460	Sensations associated with cardiovascular and respiratory functions	85
b530	Weight maintenance functions	4
b730	Muscle power functions	14
b740	Muscle endurance functions	1
b780	Sensations related to muscles and movement functions	2
s410	Structure of cardiovascular system	12
s430	Structure of respiratory system	28
s710	Structure of head and neck region	-
s720	Structure of shoulder region	-
s760	Structure of trunk	-
Additional ICF categories		
b110	Consciousness functions	2
b126	Temperament and personality functions	11
b140	Attention functions	2
b144	Memory functions	1
b160	Thought functions	1
b240	Sensations associated with hearing and vestibular function	2
b330	Fluency and rhythm of speech functions	9
b340	Alternative vocalization functions	5
b415	Blood vessel functions	1
b420	Blood pressure functions	1
b510	Ingestion functions	7
b515	Digestive functions	4
b535	Sensations associated with the digestive system	4
b545	Water, mineral and electrolyte balance functions	1
b830	Other functions of the skin	1
s310	Structure of nose	7
s330	Structure of pharynx	6
s340	Structure of larynx	1
s610	Structure of urinary system	1

1 Confirmed ICF categories of the Comprehensive ICF Core Set for OPD are shown in bold typeface.

2

1 Table 3 –Participants' reporting of ICF categories: Activities and Participation.

ICF Code	ICF Category Title	Number of linked concepts
ICF Categories of the Comprehensive ICF Core Set for OPD		
d230	Carrying out daily routine	-
d240	Handling stress and other psychological demands	12
d330	Speaking	23
d410	Changing basic body position	22
d430	Lifting and carrying objects	22
d450	Walking	48
d455	Moving around	49
d460	Moving around in different locations	1
d465	Moving around using equipment	-
d470	Using transportation	-
d475	Driving	1
d4750	Driving human-powered transportation	1
d510	Washing oneself	1
d540	Dressing	1
d570	Looking after one's health	5
d620	Acquisition of goods and services	1
d640	Doing housework	16
d650	Caring for household objects	6
d660	Assisting others	-
d770	Intimate relationships	-
d845	Acquiring, keeping and terminating a job	3
d850	Remunerative employment	2
d910	Community life	1
d920	Recreation and leisure	31
Additional ICF categories		
d210	Undertaking a single task	2
d350	Conversation	7
d415	Maintaining a body position	3
d520	Caring for body parts	2
d630	Preparing meals	2
d710	Basic interpersonal interactions	1
d720	Complex interpersonal interactions	1
d760	Family relationships	1

d930

Religion and spirituality

2

1 Confirmed ICF categories of the Comprehensive ICF Core Set for OPD are shown in bold typeface.

2

1 Table 4 –Participants' reporting of ICF categories: Environmental Factors.

ICF Code	ICF Category Title	Number of linked concepts	
ICF Categories of the Comprehensive ICF Core Set for OPD		F	B
e110	Products or substances for personal consumption	38	14
e115	Products and technology for personal use in daily living	21	-
e120	Products and technology for personal indoor and outdoor mobility and transportation	-	1
e150	Design, construction and building products and technology of buildings for public use	-	4
e155	Design, construction and building products and technology of buildings for private use	-	1
e225	Climate	-	44
e245	Time-related changes	-	9
e2450	Day/night cycles	-	8
e260	Air quality	-	81
e310	Immediate family	24	6
e320	Friends	7	-
e340	Personal care providers and personal assistants	-	-
e355	Health professionals	14	-
e410	Individual attitudes of immediate family members	11	10
e420	Individual attitudes of friends	1	-
e450	Individual attitudes of health professionals	7	5
e460	Societal attitudes	-	2
e540	Transportation services, systems and policies	2	1
e555	Associations and organizational services, systems and policies	-	1
e575	General social support services, systems and policies	-	-
e580	Health services, systems and policies	28	22
e585	Education and training services, systems and policies	-	-
e590	Labour and employment services, systems and policies	1	4
Additional ICF categories			
e210	Physical geography	2	1
e220	Flora and fauna	-	11
e235	Human-caused events	-	2
e325	Acquaintances, peers colleagues, neighbours and community members	3	-
e350	Domesticated animals	-	1
e425	Individual attitudes of acquaintances, peers colleagues, neighbours and	1	2

	community members		
e445	Individual attitudes of strangers	-	1
e515	Architecture and construction services, systems and policies	-	1
e520	Open space planning services, systems and policies	-	1
e530	Utilities services, systems and policies	-	1
e570	Social security services, systems and policies	1	-

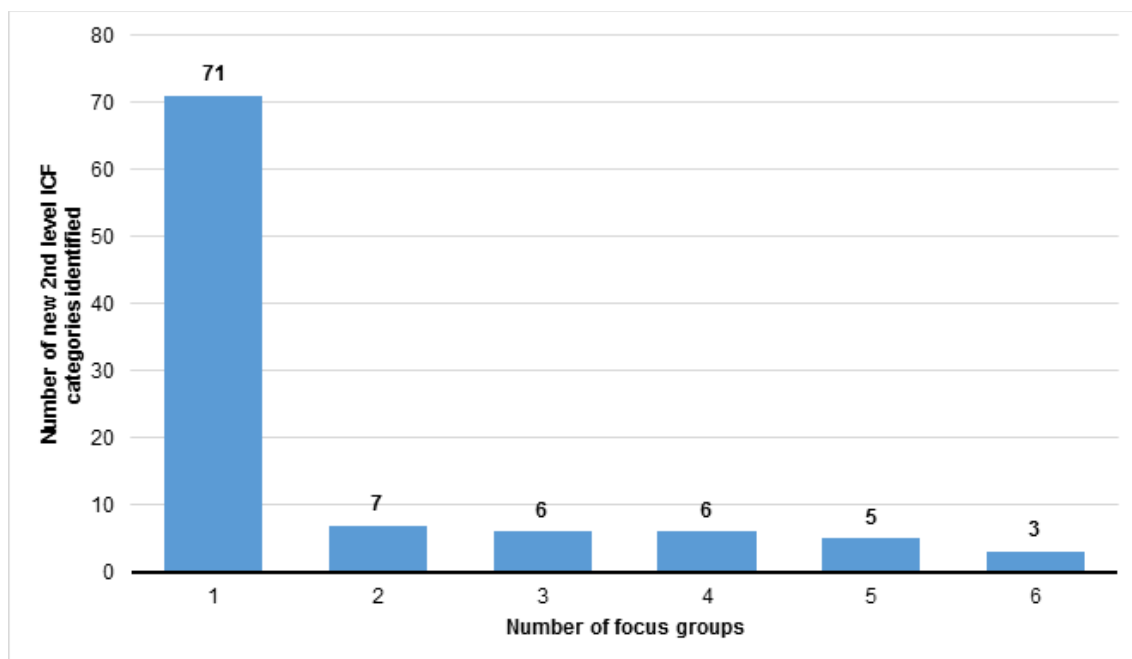
1 Confirmed ICF categories of the Comprehensive ICF Core Set for OPD are shown in bold typeface. F-facilitators; B-
2 barriers.

3

4

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1



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3 Figure 1 – Saturation of the qualitative analysis in the six focus groups.